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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,042	05/31/2005	Pallav Arvind Bulsara	PG4713USw	6188

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EXAMINER	
LOVE, TREVOR M	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
10/17/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/511,042	BULSARA ET AL.	
	Examiner	Art Unit	
	TREVOR M. LOVE	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09/12/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-4, 6-31* is/are pending in the application.

4a) Of the above claim(s) *18-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-4, 6-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/12/2008, 10/12/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made to applicant's IDS filed 09/12/2008.

Claims 18-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group I, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 07/30/2008.

Claims 1, 2, and 5 are cancelled. Claims 3-4 and 6-31 are pending. Claims 18-31 are withdrawn. Claims 3-4 and 6-17 are under consideration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-4, 6-7, 9, and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Roser et al (U.S. Patent number 6,517,860).

Roser discloses a powdered pharmaceutical composition for pulmonary delivery by inhalation comprising a bioactive agent, a surface active agent, and a hydrophobically derivatized carbohydrate (see claims 1 and 5). Said hydrophobically derivatized carbohydrate is taught as cellobiose octaacetate (see claim 15), and said powder is taught to be 1 to 4 microns (see claim 8). Furthermore the claims disclose methods such as milling (see claim 12), evaporating (see claim 10), and mixing (see claim 1). The purpose of the invention of Roser is to deliver bioactive agents to mucosal surfaces.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roser et al (U.S. Patent number 6,517,860) as applied to claim 3 above, and further in view of Blair et al (WO 02/15876).

The teachings of Roser are set forth in the section above discussing claim 3 with regards to 35 U.S.C. 102(b).

Roser fails to directly disclose what is the concentration of the derivatized carbohydrate that is taught.

Blair discloses a composition for pulmonary delivery comprising particles of a therapeutic agent and a hydrophobically derivatized carbohydrate (see claim 1). Said hydrophobically derivatized carbohydrate is present at below 5%, and preferably below 2% (see page 3, lines 27-28).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the concentrations of Blair for the invention of Roser. One would have been motivated to do so to with a reasonable expectation of success due to the analogous nature of Roser and Blair, the fact that Roser does not disclose a particular concentration, and that Blair teaches that less than 2% is preferred for a hydrophobically derivatized carbohydrate when functioning as a carrier.

Claim 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roser et al (U.S. Patent number 6,517,860) as applied to claim 3 above, and further in view of Embleton (WO 00/33789) as evidenced by Lactose.com.

The teachings of Roser are set forth in the section above discussing claim 3 with regards to 35 U.S.C. 102(b).

Roser fails to directly disclose the addition of lactose as a coarse and fine additive.

Embleton discloses a lactose fine/coarse excipient for inhalable drugs which comprises a fine component, with a particle size of less than 10 micrometers, and a coarse component, with a particle size of more than 50 micrometers (see claim 14). Lactose.com teaches that lactose as a carrier increases the stability of powder against humidity and temperature (see "Requirements for DPIs", point 3). Furthermore, Lactose.com teaches that the variable particle size of a fine/coarse combination of lactose provides for superior results (see "adhesive mixtures with fine lactose particles").

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the lactose of Embleton as an excipient in the invention of Roser. One would have been motivated to do so with a reasonable expectation of success since both Roser and Embleton disclose a composition of inhalation, comprising a drug and a carrier. Furthermore, since Roser does not teach a variable size of the carrier particles, and Lactose.com identifies the beneficial nature of such an addition, it would have been obvious to desire the lactose of Embleton as an additional excipient to the composition of Roser.

Claim 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roser et al (U.S. Patent number 6,517,860) as applied to claim 3 above, and further in view of Biggadike et al (WO 02/12266).

The teachings of Roser are set forth in the section above discussing claim 3 with regards to 35 U.S.C. 102(b), wherein Roser further discloses in claim 13 that the active agent can be an anti-inflammatory bioactive agent.

Roser fails to directly disclose that the active is the composition of either of instant claims 12 or 13.

'266 discloses both the composition of claim 12 and that of claim 13 (see page 5, line 33-page 6, line 2, claim 22). '266 teaches that the composition of claim 12 is a particularly preferred embodiment (see page 5, line 33-page 6). It is taught that the composition is useful for the treatment of inflammation (see claim 24). Furthermore, claim 25 of '266 teaches that the pharmaceutical composition '266 can be admixed with one or more physiologically acceptable diluents or carriers. Also, '266 teaches that the composition can be inhaled, and that the optimum particle size for inhalation is preferably 2-5 micrometers (see page 9, lines 20-23, and page 10, lines 29-31).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use either of the actives of '266 in the invention of Roser. One would have been motivated to do so to increase the bioavailability of the active by using the carrier of Roser over the lactose of '266 (see Roser, example 8, and '266, page 9, line 23) with a reasonable expectation of success due to the analogous nature of Roser and '266, in that both disclose a composition that is intended to be inhaled, which comprises a carrier, and is useful as an anti-inflammatory.

Claims 12-15 are rejected under 35 U.S.C. 103(a) as being obvious over Roser et al (U.S. Patent number 6,517,860) as applied to claim 3 above, and further in view of Biggadike et al (U.S. Patent number 7,135,600).

The applied reference has a **common assignee** with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art

only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The teachings of Roser are set forth in the section above discussing claim 3 with regards to 35 U.S.C. 102(b), wherein Roser further discloses in claim 13 that the active agent can be an antidepressant or an anti-inflammatory bioactive agent.

Roser fails to directly disclose that the active is the composition of any of instant claims 12-15.

'600 discloses as especially preferred embodiments both the composition of instant claim 14 and that of instant claim 15 (see column 5, lines 24-29), and specifically names the compositions of instant claims 12 and 13 as additional therapeutic agents that can be added (see claims 28 and 29). Said compositions are taught as being useful to treat inflammation or depression (see column 7, lines 16-21). Furthermore,

'600 teaches that the composition of '600 can be present with a pharmaceutically acceptable carrier (see claim 25). '600 also teaches that the composition can be administered by inhalation, and that the particle size is preferably 2-5 micrometers (see column 9, lines 28-35, and column 10, lines 16-19).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the active of '600 in the composition of Roser. One would have been motivated to do so to increase the bioavailability of the active by using the carrier of Roser over the lactose of '600 (see Roser, example 8, and '600, page 9, lines 32-34) with a reasonable expectation of success due to the analogous nature of Roser and '600, in that both disclose a composition that is intended to be inhaled, which comprises a carrier, and is useful as an anti-inflammatory or antidepressant.

Conclusion

No claims are allowed. All claims are rejected. No claims are objected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR M. LOVE whose telephone number is (571)270-5259. The examiner can normally be reached on Monday-Thursday 7:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TL

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611